(3) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(4) *pH.* Reconstitute as directed in the labeling and proceed as directed in § 436.202 of this chapter.

(5) *Identity.* The high-performance liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the cefuroxime axetil working standard.

[60 FR 27222, May 23, 1995]

§ 442.121 Cephaloglycin dihydrate oral dosage forms.

§ 442.121a Cephaloglycin dihydrate capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cephaloglycin dihydrate capsules are composed of cephaloglycin dihydrate and one or more suitable lubricants and diluents enclosed in a gelatin capsule. Each capsule contains cephaloglycin dihydrate equivalent to 250 milligrams of cephaloglycin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cephaloglycin that it is represented to contain. Its moisture content is not more than 9 percent. The cephaloglycin used conforms to the standards prescribed by § 442.21(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The cephaloglycin dihydrate used in making the batch for potency, moisture, pH, cephaloglycin content, identity, and crystallinity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The cephaloglycin dihydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of capsules into a high-speed glass blender jar with sufficient 0.1*M* potassium phosphate buffer, pH 4.5 (solution 4), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 4 to the reference concentration of 10 micrograms of cephaloglycin per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

[39 FR 19040, May 30, 1974, as amended at 50 FR 19919, May 13, 1985]

§ 442.121b Cephaloglycin dihydrate for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cephaloglycin dihydrate for oral suspension is cephaloglycin dihydrate with one or more suitable diluents, buffer substances, colorings, and flavorings. When reconstituted as directed in the labeling, each milliliter contains cephaloglycin dihydrate equivalent to 50 milligrams of cephaloglycin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cephaloglycin that it is represented to contain. Its moisture content is not more than 2 percent. When reconstituted as directed in the labeling, its pH is not less than 3.0 and not more than 5.0. It passes the identity test for the presence of the cephaloglycin moiety. The cephaloglycin dihydrate used conforms to the standards prescribed by § 442.21(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The cephaloglycin dihydrate used in making the batch for potency, moisture, pH, cephaloglycin content, identity, and crystallinity.

(*b*) The batch for potency, moisture, pH, and identity.

(ii) Samples required:

(*a*) The cephaloglycin dihydrate used in making the batch: 10 packages, each